



ASX / Media Release
12 April 2024

March Quarterly Activities Report & Appendix 4C

Invex Therapeutics Ltd (Invex, ASX:IXC, or the Company) a biopharmaceutical company focused on the development and commercialisation of Exenatide for neurological conditions relating to raised intracranial pressure (ICP), today provides an operational and corporate update to accompany its Appendix 4C cash flow statement for the quarter ended 31 March 2024 (Q3 FY24).

Operational Update

IIH EVOLVE Phase III Clinical Trial Closure

As previously indicated, Invex successfully closed out the majority of the IIH EVOLVE trial during the December 2023 quarter. During the March 2024 quarter (Q3 FY24), the Company concluded all remaining requirements associated with closing a global trial of the size and nature of the IIH EVOLVE Phase III clinical trial.

Invex successfully completed and received final audit clearance of the electronic Trial Master File (eTMF) with its Contract Research Organisation (CRO). The Company is required to hold the IIH EVOLVE clinical data for a period of two years under Good Clinical Practice in the event that a regulatory authority wishes to inspect certain data contained within the eTMF. In addition, Invex completed the necessary reporting requirements under clinicaltrials.gov and its associated Protocol Registration and Results System (PRS), which has now been approved by clinicaltrials.gov.

The final payment to the CRO under the termination agreement has been accrued by Invex and will be paid in the June 2024 Quarter (Q4 FY 24). The Company does not anticipate any further material costs associated with the IIH EVOLVE clinical trial moving forward as all contractual obligations have now been completed between Invex, the CRO and a large number of third party providers/consultants associated with the trial.

The Company's Chief Operating Officer, Ms Carol Parish completed her service with Invex on 1 February 2024. Invex expresses its sincere gratitude to Ms Parish for her service to the Company and management of the IIH EVOLVE Phase III clinical trial and its closure.

New Publication in the Prestigious EYE Scientific Journal

A new publication of Exenatide in the Journal EYE was released in January 2024 from Invex's 15 patient Phase 2 IIH clinical trial "Pressure". The major clinical findings of this Phase 2 trial were reported in May 2020. A pre-specified analysis of the effects of Exenatide on participants cognition

was undertaken. It has been demonstrated that cognitive function can be affected in conditions with raised ICP such as IIH. A number of commonly used off-label ICP lowering drugs, including acetazolamide and topiramate, have been shown to have a negative effect on patient’s cognitive function.

The Journal article entitled *“Effect of glucagon like peptide-1 receptor agonist exenatide, used as an intracranial pressure lowering agent, on cognition in Idiopathic Intracranial Hypertension”* was co-authored by Invex’s former Chief Scientific Officer Professor Alex Sinclair.

The authors concluded *“In patients with raised ICP due to IIH, exenatide, a drug emerging as an ICP lowering agent, does not adversely impact cognition. This is encouraging and has potential to be relevant when considering prescribing choices to lower ICP.”*

Corporate Development

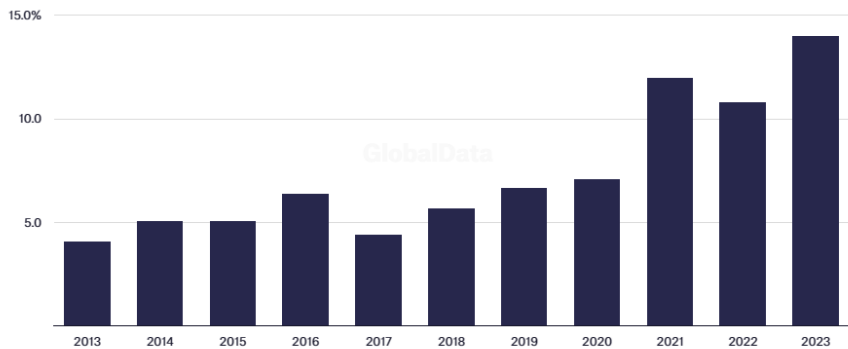
Invex is committed to the development and commercialisation of Exenatide for neurological conditions related to raised ICP. This includes a significant portfolio of issued and pending patents, and Orphan Drug Designations from the US Food and Drug Administration (FDA) and European Medicines Agency (EMA) for Idiopathic Intracranial Hypertension (IIH) and traumatic brain injury (TBI) with the EMA.

The Company continues to assess certain opportunities that may complement Invex’s existing intellectual property assets within the neurological field that aims to generate additional shareholder value over time. To date, a number of technologies have been reviewed and assessed for suitability within Invex’s pipeline noting the Company’s current cash position (\$5.5 million as at 31 March 2024); however, none are sufficiently developed to warrant further comment by the Company at this time and no binding commitments have been made.

In addition, Peptron, Inc. (KOSDAQ: 087010), Invex’s former manufacturing partner has been granted a first right of refusal for global development rights of Exenatide in IIH. The class of drugs, GLP-1 receptor agonists (GLP-1RAs) of which Exenatide is a member, have seen significant clinical trial investment in diabetes and obesity. Near 15% of all clinical trials outside of diabetes and obesity with a GLP-1RA remaining ongoing, of which 10% are central nervous system related.

The percentage of trials investigating GLP1RAs in alternative indications peaked last year

The percentage of clinical trials using GLP1RAs in indications other than diabetes and obesity, by year of initiation.



Note: Data as of 09 February 2024. The data excludes all clinical trials investigating GLP1RAs in diabetes and obesity. Source: GlobalData’s Pharmaceutical Intelligence Center

Accordingly, Invex continues to investigate the use of Exenatide in other ICP related disorders including TBI, hydrocephalus and stroke. This is consistent with the Company's strong IP within this segment. In addition, the Company has generated some early promising data in the eye-related pressure disease, glaucoma.

Corporate Update

UK R&D Tax Incentive

On 5 March 2024, Invex provided an update on the receipt of the UK FY23 R&D tax claim, which had been anticipated in December 2023, consistent with prior years.

Due to changes introduced from April 2023, the processing of claims by the UK HM Revenue and Customs (HMRC) has been significantly delayed. The HMRC has not provided the Company and its advisors with any further guidance as to the processing and payment timeline of the FY23 rebate.

The Company's FY23 claim was for an amount of £633k (A\$1.23 million) through the Company's wholly owned UK subsidiary. There is no certainty as to the timing of receipt of funds; however, Invex and its UK tax advisors remain confident the claim will be paid.

Capital Return

On 20 March 2024 Invex announced the Australian Taxation Office (ATO) had published a Class Ruling (CR 2024/17) in relation to Invex's \$0.14 per share return of capital announced on 31 October 2023 and paid on 18 December 2023.

The ATO Class Ruling confirmed that no part of the capital return will be assessable as a dividend for Australian taxation purposes for Invex shareholders. The tax consequences for a Shareholder with respect to the Capital Return may vary depending upon the Shareholder's individual circumstances. Shareholders should consult their own tax adviser as to the potential tax consequences for them with respect to the Capital Return. The ruling can also be viewed or download from the ATO website at www.ato.gov.au/law.

Currently Invex notes that approximately 100 shareholders representing unclaimed capital return proceeds of approximately \$0.25 million were outstanding as at 8 April 2024.

The record date for shareholders eligible to receive the capital return of approximately \$0.19 per share was Monday 11 December 2023. A shareholder of Invex on the Record Date will be entitled to receive the capital return. Automatic share registry will not be issuing bank cheques to eligible shareholders who are entitled to receive the capital return. **Invex strongly encourages those shareholders yet to provide banking details to do so as soon as possible.**

In order for holders to update banking details, the share registry's online Investor Portal can be located at <https://investor.automic.com.au/#/home>.

Alternatively, shareholders can complete and return a Direct Credit Facility form at https://automic.com.au/form/Direct_Credit_Facility.pdf. Investors who have not registered their direct credit details to facilitate payment of the capital return are urged to contact the Share registry on 1300 288 664 (or on +61 (0) 2 9698 5414 if calling from outside or Australia) or email at hello@automic.com.au.

Financial Summary and Analysis

The Company closed the quarter with cash and cash equivalents of \$5.5 million (Q2 FY24: \$6.2 million), with overall operating cash outflows for the quarter of \$0.70 million (Q2 FY24: \$1.1 million) and financing cash outflow of Nil (Q2 FY24: \$14.0 million – the capital return).

Cash outflows from operating expenditure included:

- Research & Development expenditure for the quarter of \$0.25 million (versus \$0.78 million in Q2 FY24) reflecting costs associated with the Company's contract research organisation managing the close out of IIH EVOLVE, along with close out of clinical and regulatory consultants, and intellectual property costs related to Invex's patent and trademark portfolio. In addition, the Company incurred costs associated with direct R&D staff of \$0.14 million (versus \$0.20 million in Q2 FY24). The Company no longer has any R&D employees retained within its UK subsidiary.
- Administration and corporate costs of \$0.37 million (versus \$0.23 million in Q2 FY24) include legal, share registry and tax compliance costs related to the capital return and close out of IIH-EVOLVE in addition to the compliance costs associated with an ASX listed company, Director's fees, audit and legal costs.
- Interest received on cash deposits held of \$0.058 million (versus \$0.15 million in Q2 FY24). Following the capital return, interest on cash will decline in future periods consistent with the overall lower cash position.

Aggregate amounts paid to related parties of the Company and their associates included in the above costs were \$0.28 million for the quarter.

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This release dated 12 April 2024 has been authorised for lodgement to ASX by the Board of Directors of Invex Therapeutics.

For more information, please contact:

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About Invex Therapeutics Ltd

Invex is a biopharmaceutical company focused on the repurposing of an already approved drug, Exenatide, for efficacious treatment of neurological conditions derived from or involving raised intracranial pressure. Invex has trademarked its repurposed Exenatide as Presendin™. www.invextherapeutics.com.

Appendix 4C

Quarterly cash flow report for entities subject to Listing Rule 4.7B

Name of entity

Invex Therapeutics Ltd

ABN

29 632 145 334

Quarter ended ("current quarter")

31 March 2024

Consolidated statement of cash flows	Current quarter \$A'000	Year to date (9 months) \$A'000
1. Cash flows from operating activities		
1.1 Receipts from customers	-	-
1.2 Payments for		
(a) research and development	(245)	(1,967)
(b) product manufacturing and operating costs	-	-
(c) advertising and marketing	-	-
(d) leased assets	-	-
(e) staff costs – R&D	(143)	(565)
(f) administration and corporate costs	(369)	(827)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	58	435
1.5 Interest and other costs of finance paid	-	-
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	-	-
1.8 Other – (D&O insurance)	-	(92)
1.9 Net cash (used in) operating activities	(699)	(3,016)
2. Cash flows from investing activities		
2.1 Payments to acquire:		
(a) entities	-	-
(b) businesses	-	-
(c) property, plant and equipment	-	-
(d) investments	-	-
(e) intellectual property	-	-

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (9 months) \$A'000
	(f) other non-current assets	-	-
2.2	Proceeds from disposal of:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	-	-
	(d) investments	-	-
	(e) intellectual property	-	-
	(f) other non-current assets	-	-
2.3	Cash flows from loans to other entities	-	-
2.4	Dividends received (see note 3)	-	-
2.5	Other (provide details if material)	-	-
2.6	Net cash from / (used in) investing activities	-	-

3.	Cash flows from financing activities		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	-	-
3.2	Proceeds from issue of convertible debt securities	-	-
3.3	Proceeds from exercise of options	-	-
3.4	Transaction costs related to issues of equity securities or convertible debt securities	-	-
3.5	Proceeds from borrowings	-	-
3.6	Repayment of borrowings	-	-
3.7	Transaction costs related to loans and borrowings	-	-
3.8	Dividends paid	-	-
3.9	Other – capital return	-	(14,001)
3.10	Net cash from / (used in) financing activities	-	(14,001)

4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	6,152	22,470
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(699)	(3,016)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	-	-

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (9 months) \$A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	-	(14,001)
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	Cash and cash equivalents at end of period	5,453	5,453

5.	Reconciliation of cash and cash equivalents at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts	Current quarter \$A'000	Previous quarter \$A'000
5.1	Bank balances	403	1,102
5.2	Call deposits	5,050	5,050
5.3	Bank overdrafts	-	-
5.4	Other (provide details)	-	-
5.5	Cash and cash equivalents at end of quarter (should equal item 4.6 above)	5,453	6,152

6. Payments to related parties of the entity and their associates

6.1 Aggregate amount of payments to related parties and their associates included in item 1

6.2 Aggregate amount of payments to related parties and their associates included in item 2

**Current quarter
\$A'000**

276

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Note: if any amounts are shown in items 6.1 or 6.2, your quarterly activity report must include a description of, and an explanation for, such payments

Relates to salaries, consulting and fees paid to Directors. Payments of \$45,000 for company secretarial accounting and financial services to Concept Biotech of which Mr McAuliffe is a director and shareholder are included.

7. Financing facilities

Note: the term "facility" includes all forms of financing arrangements available to the entity.

Add notes as necessary for an understanding of the sources of finance available to the entity.

- 7.1 Loan facilities
- 7.2 Credit standby arrangements
- 7.3 Other (please specify)
- 7.4 **Total financing facilities**

	Total facility amount at quarter end \$A'000	Amount drawn at quarter end \$A'000
	-	-
	-	-
	-	-
	-	-

7.5 Unused financing facilities available at quarter end

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- 7.6 Include in the box below a description of each facility above, including the lender, interest rate, maturity date and whether it is secured or unsecured. If any additional financing facilities have been entered into or are proposed to be entered into after quarter end, include a note providing details of those facilities as well.

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8. Estimated cash available for future operating activities**\$A'000**

8.1	Net cash from / (used in) operating activities (Item 1.9)	(699)
8.2	Cash and cash equivalents at quarter end (Item 4.6)	
8.3	Unused finance facilities available at quarter end (Item 7.5)	-
8.4	Total available funding (Item 8.2 + Item 8.3)	8
8.5	Estimated quarters of funding available (Item 8.4 divided by Item 8.1)	

- 8.6 If Item 8.5 is less than 2 quarters, please provide answers to the following questions:

1. Does the entity expect that it will continue to have the current level of net operating cash flows for the time being and, if not, why not?

Answer:

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2. Has the entity taken any steps, or does it propose to take any steps, to raise further cash to fund its operations and, if so, what are those steps and how likely does it believe that they will be successful?

Answer:

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3. Does the entity expect to be able to continue its operations and to meet its business objectives and, if so, on what basis?

Answer:

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Compliance statement

- 1 This statement has been prepared in accordance with accounting standards and policies which comply with Listing Rule 19.11A.
- 2 This statement gives a true and fair view of the matters disclosed.

Date: 12 April 2024

Authorised by: Narelle Warren
(On behalf of the Board of Directors)

Notes

1. This quarterly cash flow report and the accompanying activity report provide a basis for informing the market about the entity's activities for the past quarter, how they have been financed and the effect this has had on its cash position. An entity that wishes to disclose additional information over and above the minimum required under the Listing Rules is encouraged to do so.
2. If this quarterly cash flow report has been prepared in accordance with Australian Accounting Standards, the definitions in, and provisions of, *AASB 107: Statement of Cash Flows* apply to this report. If this quarterly cash flow report has been prepared in accordance with other accounting standards agreed by ASX pursuant to Listing Rule 19.11A, the corresponding equivalent standard applies to this report.
3. Dividends received may be classified either as cash flows from operating activities or cash flows from investing activities, depending on the accounting policy of the entity.
4. If this report has been authorised for release to the market by your board of directors, you can insert here: "By the board". If it has been authorised for release to the market by a committee of your board of directors, you can insert here: "By the [name of board committee – eg Audit and Risk Committee]". If it has been authorised for release to the market by a disclosure committee, you can insert here: "By the Disclosure Committee".
5. If this report has been authorised for release to the market by your board of directors and you wish to hold yourself out as complying with recommendation 4.2 of the ASX Corporate Governance Council's *Corporate Governance Principles and Recommendations*, the board should have received a declaration from its CEO and CFO that, in their opinion, the financial records of the entity have been properly maintained, that this report complies with the appropriate accounting standards and gives a true and fair view of the cash flows of the entity, and that their opinion has been formed on the basis of a sound system of risk management and internal control which is operating effectively.